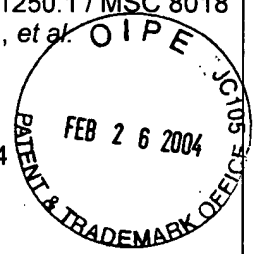


<p align="center"><b>DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION</b></p> <p><input type="checkbox"/> Declaration submitted with original filing</p> <p>or</p> <p><input checked="" type="checkbox"/> Declaration submitted after initial filing</p>	<p>Attorney Docket Number: B185 1250.1 / MSC 8018 First Named Inventor: Kang Cai, et al.</p> <p><i>Complete if Known:</i></p> <p>Application Number: 10/693,734 Filing Date: October 23, 2003 Group Art Unit: Unassigned Examiner Name: Unassigned</p>
--	--



As an inventor named below, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below), or, an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**A RAPID METHOD OF DETERMINING CLEARANCE OF PRION PROTEIN**

The specification of which:

- ☐ is attached hereto;
- ☐ was Express Mailed on \_\_\_\_\_, Serial No. not yet known;
- ☒ was filed on October 23, 2003, as United States Application Serial No. 10/693,734;
- ☐ was amended on \_\_\_\_\_;
- ☐ was described and claimed in International Application No. PCT \_\_\_\_\_, filed on \_\_\_\_\_, and as amended under PCT Article 19 on \_\_\_\_\_.

I hereby state that I have reviewed and understand the contents of the specification identified above, including the claims, as amended in any amendment referred to above.

I acknowledge my duty to disclose to the United States Patent Office all information which is known to me to be material to patentability as defined in 37 CFR §1.56.

Priority Claim under 35 USC §119(e):

I hereby claim the benefit under 35 USC §119(e) of any United States provisional application(s) listed below.

☐ None

Application Serial Number	Filing Date (Day/Month/Year)

Priority Claim under 35 USC §120 or §365(c):

I hereby claim the benefit under 35 USC §120 of any previously filed United States non-provisional application(s), including original, divisional, continuation and continuation-in-part application(s), or claim the benefit under 35 USC §365(c) of any PCT International application(s) designating the United States that are listed below.

☐ None

Application Serial Number	Filing Date (Day/Month/Year)	Status

Insofar as the subject matter of each of the claims of this application is not disclosed in the above prior United States or PCT International application(s) in the manner provided by the first paragraph of 35 USC §112, I acknowledge my duty to disclose to the United States Patent Office all information which is known to me to be material to patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Priority Claim under 35 USC §119(a)(b) and (d) or §365(a) and (b):

I hereby claim foreign priority benefits under 35 USC §119(a)(b) and (d) and §365(a) and (b) of any foreign application(s) for patent or inventor's certificate, or any PCT International application(s) designating at least one country other than the United States, listed below.

☐ None

Application Serial Number	Country	Filing Date (Day/Month/Year)

Foreign Application(s) filed before the priority document(s) under 35 USC §119(c) and 37 CFR §1.63(c):

I have also identified below any foreign application for patent or inventor's certificate, or PCT International application designating at least one country other than the United States filed by me on the same subject matter and having a filing date before that of the application(s) from which foreign priority is claimed, whether abandoned or not.

☐ None

Application Serial Number	Country	Filing Date (Day/Month/Year)

As a named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith.

MARY G. BOGUSLASKI, PH.D., Reg. No. 31,486  
LOUIS T. ISAF, Reg. No. 29,078  
STEVEN D. KERR, Reg. No. 32,472  
JOHN J. TIMAR, Reg. No. 32,497  
DAVID J. HAYZER, Reg. No. 43,329  
CARL B. MASSEY, JR., Reg. No. 44,224  
C. ROBERT RHODES, Reg. No. 24,200  
JEFFREY R. MCFADDEN, Reg. No. 46,916  
CRAIG H. POPALIS, Reg. No. 49,028  
PAUL KIMBALL, Reg. No. 34,601  
BARRY S. GOLDSMITH, Reg. No. 39,690  
KEATS A. QUINALTY, Reg. No. 46,426

JEFFREY GREENMAN, Reg. No. 26,552  
JAMES F. VAUGHAN, Reg. No. 31,889  
D. SCOTT SUDDERTH, Reg. No. 34,026  
STEVEN L. SCHMID, Reg. No. 39,358  
DAVID S. BRADIN, Reg. No. 37,783  
THOMAS B. MCGURK, Reg. No. 44,920  
JACK B. HICKS, Reg. No. 34,180  
LEWIS S. ROWELL, Reg. No. 45,469;  
DALE C. HOGUE, SR., Reg. No. 32,823  
IAN A. CALVERT, Reg. No. 50,186  
NANDA K. ALAPATI, Reg. No. 39,893  
WILLIAM A. CAPP, Reg. No. 49,037


Direct all telephone calls to Carl B. Massey, Jr. at (336) 721-3681.

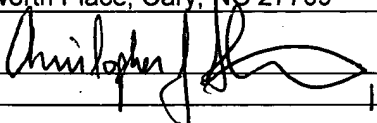
Address all written correspondence to:

Customer No. 26158

**Carl B. Massey, Jr.**  
**WOMBLE CARLYLE SANDRIDGE & RICE, PLLC**  
**Post Office Box 7037**  
**Atlanta, Georgia 30357-0037**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Inventor (First/Middle/Last): Kang Cai  
Country of Citizenship U.S.A.  
Residence (City, State, Country): 102 Bay Colony Court; Chapel Hill, NC 27517  
Post Office Address: 102 Bay Colony Court; Chapel Hill, NC 27517  
Inventor's Signature:   
Date: 12/16/2003

Name of Inventor (First/Middle/Last): Christopher J. Stenland  
Country of Citizenship U.S.A.  
Residence (City, State, Country): 102 Mereworth Place; Cary, NC 27709  
Post Office Address: 102 Mereworth Place; Cary, NC 27709  
Inventor's Signature:   
Date: 12/16/2003



Attorney Docket No. B185 1250.1  
(MSC 8018)

### ASSIGNMENT OF INVENTION

In consideration of the payment by ASSIGNEE to ASSIGNOR of the sum of one dollar (\$1.00) and for other good and valuable consideration, the receipt of which is hereby acknowledged,

ASSIGNOR(S):

Name of Inventor (Last name followed by given name)	Address	Country of Citizenship
Kang Cai	102 Bay Colony Court Chapel Hill, NC 27517	U.S.A.
Christopher J. Stenland	102 Mereworth Place Cary, NC 27709	U.S.A.

hereby sell(s), assign(s) and transfer(s) to

ASSIGNEE: Bayer HealthCare LLC, 555 White Plains Road, Tarrytown, New York 10591, United States of America, a corporation organized under the laws of the State of Delaware, United States of America, and its successors, assigns and legal representatives,

the entire right, title and interest in and to, including the right to claim priority from, the invention(s) disclosed in U.S. Patent Application Serial Number 10/693,734, filed on October 23, 2003,

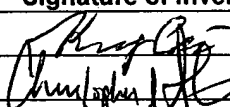
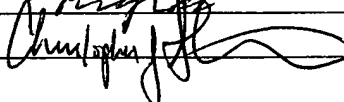
which is entitled: A Rapid Method of Determining Clearance of Prion Protein

and any legal equivalent thereof in a foreign country,

and in and to all Letters Patent and equivalents thereof to be obtained for said invention in all countries by the above application or any continuation, division, renewal, substitute or equivalent thereof, as well as to any reissue, reexamination, patent term restoration, or equivalent thereto.

ASSIGNOR hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment, and that ASSIGNEE will, upon ASSIGNEE's request, be provided promptly with all pertinent facts and documents relating to said invention(s) and said Letters Patent and legal equivalents as may be known and accessible to ASSIGNOR, and ASSIGNOR will testify as to the same in any interference, litigation or other proceeding related thereto, and will promptly execute and deliver to ASSIGNEE or its legal representative(s) any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue and enforce said application, said invention(s) and said Letters Patent and said equivalents thereof which may be necessary or desirable to carry out the purposes thereof.

IN WITNESS WHEREOF, I/we have hereunto respectively set hand and seal on the date(s) shown below:

Typed Name of Inventor	Signature of Inventor	Date
Kang Cai		12/16/2003
Christopher J. Stenland		12/16/2003

## POWER OF ATTORNEY FROM ASSIGNEE

Bayer HealthCare, LLC, a Delaware Corporation, is Assignee of the entire right, title and interest for the United States of America (as defined in 35 U.S.C. § 100) of an invention known as, A RAPID METHOD OF DETERMINING CLEARANCE OF PRION PROTEIN, which is disclosed and claimed in a patent application of the same title by reason of Assignment to the Assignee executed on Dec. 16, 2003, by the inventor Kang Cai, and executed on Dec 16, 2003, by the inventor Christopher J. Stenland, said application filed October 23, 2003, at the U.S. Patent and Trademark Office, having Application No. 10/693,734.

The Assignee hereby appoints the following attorneys to prosecute this application and such division, continuation, and reissue applications thereof as are filed by them on behalf of the Assignee, and to transact all business in the U.S. Patent and Trademark office connected therewith:

LOUIS T. ISAF, Reg. No. 29,078  
STEVEN D. KERR, Reg. No. 32,472  
JOHN J. TIMAR, Reg. No. 32,497  
DAVID J. HAYZER, Reg. No. 43,329  
CARL B. MASSEY, JR., Reg. No. 44,224  
C. ROBERT RHODES, Reg. No. 24,200  
JEFFREY R. MCFADDEN, Reg. No. 46,916  
CRAIG H. POPALIS, Reg. No. 49,028  
PAUL KIMBALL, Reg. No. 34,601  
BARRY S. GOLDSMITH, Reg. No. 39,690  
KEATS A. QUINALTY, Reg. No. 46,426

JAMES F. VAUGHAN, Reg. No. 31,889  
D. SCOTT SUDDERTH, Reg. No. 34,026  
STEVEN L. SCHMID, Reg. No. 39,358  
DAVID S. BRADIN, Reg. No. 37,783  
THOMAS B. MCGURK, Reg. No. 44,920  
JACK B. HICKS, Reg. No. 34,180  
LEWIS S. ROWELL, Reg. No. 45,469;  
DALE C. HOGUE, SR., Reg. No. 32,823  
IAN A. CALVERT, Reg. No. 50,186  
NANDA K. ALAPATI, Reg. No. 39,893  
WILLIAM A. CAPP, Reg. No. 49,037

Assignee hereby grants said attorneys the power to insert on the Power of Attorney any further identification which may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

Send Correspondence to:

Carl B. Massey, Jr.  
Womble Carlyle Sandridge & Rice, PLLC  
Post Office Box 7037  
Atlanta, Georgia 30357-0037

Direct phone calls to: (336) 721-3681

FOR:	<u>Bayer HealthCare, LLC</u>
BY:	<u>Mary G. Boguslaski, Ph.D.</u>
TITLE:	<u>Senior Patent Counsel</u>
SIGNATURE:	<u>Mary G. Boguslaski</u>
DATE:	<u>December 17, 2003</u>

Certificate Under 37 C.F.R. § 3.73(b)



Applicants: Cai, et al.  
Application No.: 10/693,734 Filed: October 23, 2003

For: A RAPID METHOD OF DETERMINING CLEARANCE OF PRION PROTEIN

Bayer HealthCare LLC

a corporation

(Name of Assignee)

(Type of Assignee, e.g. corporation, partnership, university, government agency, etc.)

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. ☒ An Assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or which a copy thereof is attached.
2. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or which a copy thereof is attached.
3. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements are made on information and belief to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Name: Mary G. Boguslaski, Ph.D., J.D.

Date: December 17, 2003

Title: Senior Patent Counsel, Bayer HealthCare LLC

Signature: Mary G. Boguslaski



## EXPRESS MAIL CERTIFICATE

"Express Mail" mailing label number : EL 984 914 795 US

Date of Deposit : February 26, 2004

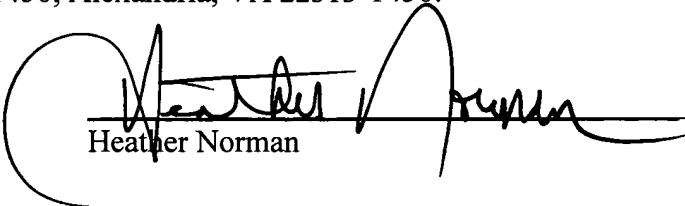
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NonProvisional Patent Application;  
Part 2 – Copy of Notice to File Missing  
Parts of NonProvisional Application;  
Fee Transmittal;  
Declaration for Patent Application;  
Assignment;  
Power of Attorney from Assignee;  
Certificate under 37 CFR 3.73(b);  
Information Disclosure Statement;  
Form 1449;  
Cited references / twelve (12); and  
Return Postcard

Serial No. : 10/693,734

Filing Date : October 23, 2003

I hereby certify that the documents identified above are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and are addressed to the Commissioner for Patents, Mail Stop:

MISSING PARTS; P.O. Box 1450, Alexandria, VA 22313-1450.

 (signature)  
Heather Norman